Yirro-plus® Premium

gebruikshandleiding / user manual / Benutzeranleitung / mode d'emploi

zelfreinigend mondspiegelsysteem / self-cleaning dental mirror system / selbstreinigender Mundspiegelsystem / système de miroir dentaire d'auto-nettoyage

versie December 2013 / version December 2013 / Version Dezember 2013 / version Decembre 2013

www.Yirro-plus.com

Deze gebruikshandleiding is met de grootst mogelijke zorg samengesteld.
Mocht u desondanks van mening zijn dat de inhoud van deze handleiding niet volledig of onjuist is, stuur uw opmerkingen of verbetersuggesties naar service@dhm-dental.com.

This manual has been compiled with care.
If you have any remarks please inform us at service@dhm-dental.com

Dieser Manual wurde mit Sorg zusammengestellt.
Sollten Sie Bemerkungen oder Tips haben, so melden Sie diese bie uns über service@dhm-dental.com.

Ce mode d'emploi a été réalisé avec le plus grand soin.
Si pourtant vous avez des rémarques, veuillez-les communiquer à service@dhm-dental.com.

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UK user instructions

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declaration of conformity

This declaration of conformity contains the unique identification number DHMD/CV01#2 and is published by DHM-dental BV, located on Grand Vijverdal 27, 6822 MB, Arnhem, NL. The subject of concern is a medical device in class 1 with registered trademark named Yirro-plus ® to be described as a self-cleaning dental mirror system, produced by DHM-Dental BV, Arnhem in the Netherlands.

DHM-dental BV hereby declares that the Yirro-plus® system meets all the requirements that professional users may reasonably expect of a self-cleaning dental mirror system. During the development we have cooperated with expert users. Prior to the launch both this product and its manual were tested by expert users and service technicians to optimize the usability, implentation and reliability.

The Yirro-plus® system complies with the following directives and standards:

EN 980, Symbols for use in the labelling of medical devices
EN 1041, Information supplied by the manufacturer with medical devices
EN 1639, Dentistry — Medical devices for dentistry — Instruments
EN 1640, Dentistry — Medical devices for dentistry — Equipment
EN-ISO 9873:2000, Dental hand instruments - reusable mirrors and handles
EN-ISO 9687, Dental equipment — Graphical symbols
ISO 13402:1995, Surgical and dental hand instruments — determination of resistance against autoclaving, corrosion and thermal exposure
EN-ISO 14971, Medical devices — application of risk management to medical devices
EN 21942-1/3/4, Dental vocabulary — Part 1: General and clinical terms
— Part 3: Dental instruments — Part 4: Dental equipment
EN 23964, Dentistry — Dental handpieces — Coupling dimensions
EN 60601-1, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

93/42/EEG (Medical devices, general rules)

This declaration of conformity is drawn up in Arnhem, Netherlands, on December 14th 2013 by DGA DHM-dental BV.

signature:

This declaration of conformity was first issued on October 1, 2013 and is of unlimited duration, but not siginificant change as long as the conditions that are described in the technical documentation or the manufacturing conditions in the factory or the process of quality control.

UK - english

general description

generic description

The Yirro-plus® system is a selfcleaning dental mirror system in the Classe I of medical products (*).

Product description

This product is developed for professional dental experts. Its self-cleaning function is based on an air flow constantly cleaning the mirror, thus offering its user a permanent sight.

Yirro-plus® Premium

The system contains of a detachable mirror head [1], placed on a hollow handle [2] that is detachably connected to the central press-air station by an flexible silicon air-hose. The detachable magnet-coupler [3] at the end of this air-hose is to be parked in a docking station. The parking and lifting of the magnet-coupler automatically switches on-and-off the air flow. Beneath the docking the air-regulator [5] is situated, containing a turning knob for air-regulation. The system is to be installed independantly to the central press-air and the eletricity-net by a set of components consisting of a connection hose [6] and a Power/Air supply box (see p. 6 [7,8,9].) The components of the system can be cleaned by the usual methods.

exclusion

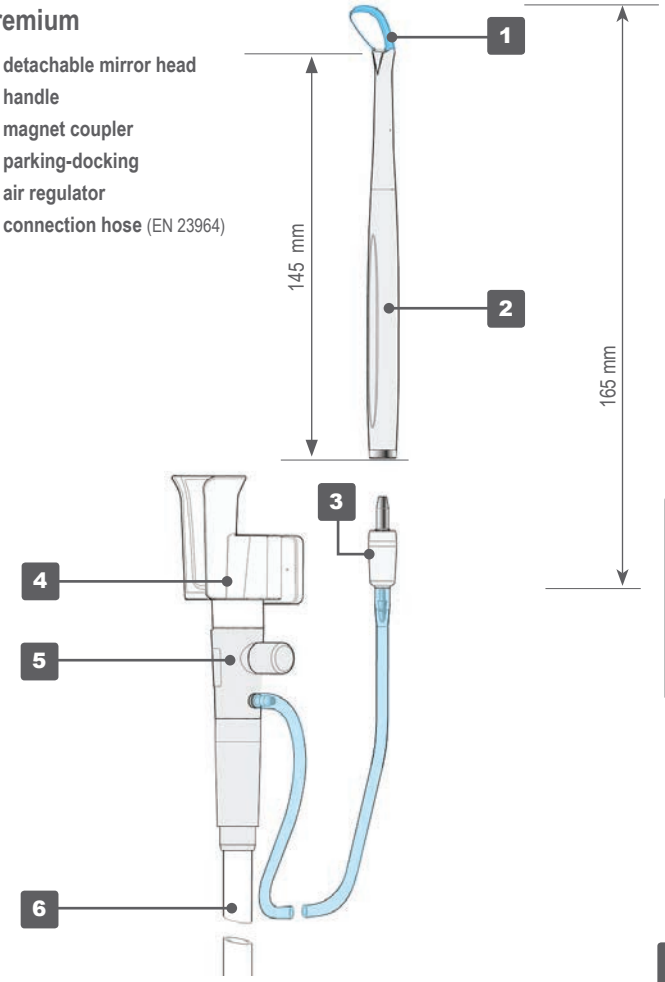
exclusion

The Yirro-plus® system is NOT intended as a multi-function syringe or general tool for your assistent. The system is NOT meant to be connected to water or air-suction. Yirro-plus® handles are NOT meant to be used as an instrument without the mirror head. The magnet coupler [3] is NOT to be cleaned in the autoclave; it might lose its magnetism. The connection hose [6] is NOT meant to be connected to other instruments.

(*) According to classification in annex IX from the European Rules for medical products.

Premium

[1] detachable mirror head
[2] handle
[3] magnet coupler
[4] parking-docking
[5] air regulator
[6] connection hose (EN 23964)



variety of Yirro-plus® programme

Premium
The Premium basic set is an independant complete system, universal applicability. The set contains: 2 boxes of handles with in total 8 plastic handles, 2 boxes of mirrors with in total 12 mirror heads (6x type 'Triade 0'; 6x type 'Triade no. 2'), 1 magnet-air-coupling, 1 parking-docking, 1 air regulator, 1 Power/Air supply box with solenoid valve and connection hose, 1 user manual and 1 disclaimer.

mirror box Triade no. 2 (size big)
1 box with 6 mirror heads no. 2 (18.4 mm), user instruction / disclaimer

mirror box Triade no. 0 (size small)
1 box wit 6 mirror heads no. 1 (13.2 mm), user instruction / disclaimer

handle box
1 box with 4 handles (durable plastic); user instruction / disclaimer

cleaning box *(from spring 2014)*
cleaning box for protected cleaning of 6 mirror heads

material specifications

durable, scratch-safe and secure materials
The Yirro-plus® handles and mirror heads are produced from high quality heat resistant and durable plastic. The mirror head contains a glass mirror with ultra-reflection surface. The base contains a metal ring of stainless steel and its weight is only 11,5 grammes.

The housing of the Yirro-plus® air-coupler is produced from durable and scratch-safe plastic; with attached to it an silicon air-hose.The air-hose is mounted on both sides into a metal nipple.

The parking-docking is fabricated of a durable plastic, resistant to the usual cleaning procedures by alcohol or desinfectants. The air regulator and regulation knob are composed of preserved metal components.

heat resistant, safe adhesive joints and coatings
All adhesives and coatings used in assembly are heat-resistant and absolutely safe for this application.

reliable accessories
The parking docking is mounted with a standard connection-hose produced by the **EN 23964** directive. All components meet medical safety guidelines.

packaging, brochures
Our brochures, packaging and cartons are printed on recyclable paper and cardboard.

N.B. None of our products are sterile; please clean before use.

product safety

safe in use

The Yirro-plus® system is a safe system provided it is used with care and in the way it is meant to be used.

no danger or nuisance

This dental mirror does not contain any sharp parts or edges that might hurt patient or the user. The on/off switching or the regulation of air does not enable any dangerous situations.By use of this product no hinder or nuisance for dentist or patient is caused nor do any gasses or 'stoffen' occur that are dangerous for the health of patient or user. This product has been tested thoroughly by expert users in this respect.

standards and regulations

For this product the following directions have been applied:

EN 980, Symbols for use in the labelling of medical devices
EN 1041, Information supplied by the manufacturer with medical devices
EN 1639, Dentistry — Medical devices for dentistry — Instruments
EN 1640, Dentistry — Medical devices for dentistry — Equipment
EN-ISO 9873:2000, Dental hand instruments - reusable mirrors and handles
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EN 60601-1, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
93/42/EEG (Medical devices, general rules)

compatibility

compatible with every type of dental unit

The Yirro-plus® system is universal and can be installed independantly of the type of dental unit.

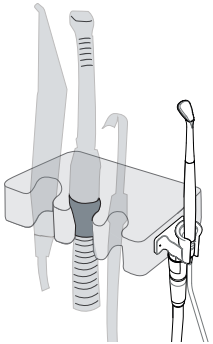
prescribed mounting

universal mounting system

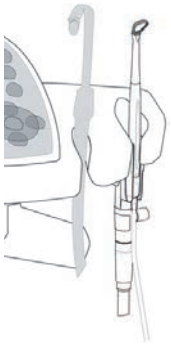
Yirro-plus® is preferrably mounted by use of the universal mounting system; placed sideways of the dental assistance unit on the side of the 'mirror hand'.

mounting by use of the docking-adaptor

When a free slot is available it is possible to mount the Yirro-plus ® system directly into the assistance unit, by use of the included docking-adaptor.



prescribed mounting (CE)



mounting in docking-adaptor

Note that installation in docking-adaptor is NOT covered by the CE marking of the Yirro-plus® system.

quality policy & reviews

quality Yirro-plus®
Yirro-plus® is manufactured according to EN / ISO 13485 standard, and the quality is of the greatest importance, from product development to implementation and expedition. Should nevertheless occur the case that this product does not meet your expectations, you may contact the customer service department; service@dhm-dental.com.

product development
The development of this product has been concluded in close consultation with expert users, whereby every step and solution has been tested and verified. Important aspects such as ease of use, comfort, functionality, safety and hygiene were assessed and this interactive process has contributed to the design, weight, aspects, choice of materials and production of the whole system.

reviews - postmarket surveys
It is our wish that the Yirro-plus® system is regularly reviewed by expert users. Take a look at our social media accounts on Twitter and Facebook (see links on http://www.dhm-dental.com/socialmediaNL.html.) We kindly invite you to give your personal opinion about our product.

safety measures

safety instructions
Use the Yirro-plus® dental mirror only for the view of your workspace and put it back in place after every patient treatment. The system is to be cleaned after every treatment by using the regular hygiëne procedures as described. Do not place the magnet-coupling near by the heart of the patiënt, for potential influence of pacemakers.

Do NOT clean the detachable magnet-coupler in the autoclave, since its magnetic force might be lost. Clean the detachable couplers properly with alcohol or disinfectant.

installation by a qualified technician

installation
Your Yirro-plus ® system is to be installed by a qualified technician. You can instruct your technician to install an independant system by use of included components, to be connected with the main electricity and compressed-air system. For connection instructions see aside.

right spot
Decide in advance whether you will use the universal mounting system (CE). Maybe you prefer the use of the adapter-rings. (See for this the 2 options visualised at page 21). Check the length of the connection hose and the (thin) silicon air hose. After installation the Yirro-plus® parking docking can be mounted. For this see the steps described at pages 23-25.

instructions for independant connection

Your service technician (*) enables an independant connection to the electricity net and a connection to your compressed air system. For this purpose, in the Premium set of Yirro-plus® all necessary components are included. They concern a Medical transformator (100-240 VAC - 50-60 Hz with output 24Volt DC) and a connection box with in it an integrated 24Volt regulation system and standard connection supplies. Beneath you will find the over view of the connection components and underneath the installation ‘instruction’.

instruction
- split ‘air’ by making use of T-part R 3/8 [8]
- create an electrical connection for Power Adapter [9]

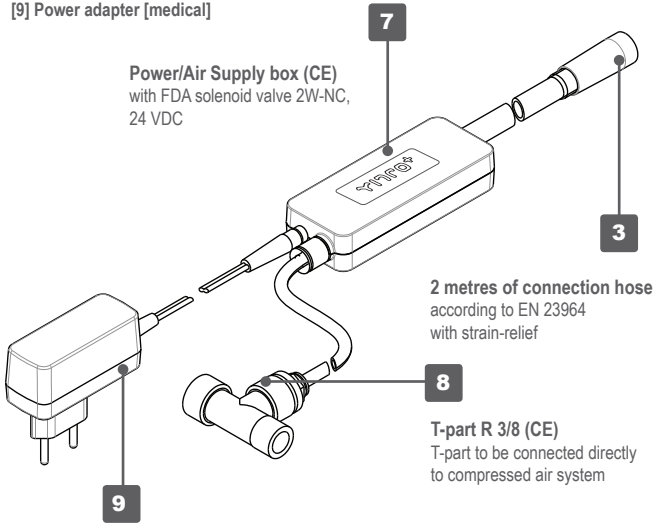
Connect Power adapter togehter with contra plug into the electricity and put the end (plug) in Power/Air Supply box [7]. Connect the end of the Air Tube fitting to the Power/Air Supply box.

(*) The CE-marking for this product prescribes that installation of the system is to be carried out by an authorized service technician.

mounting parts for installation

[3] connection hose (EN 23964)

[7] Power/Air Supply box
[8] T-part R 3/8
[9] Power adapter [medical]



(**) Despite the fact that it is technically possible to connect this system directly to 24V DC this is not recommended. Direct connection may conflict with the warranty and CE requirements of your unit. Consequently direct connection is not covered by the CE marking of the Yirro-plus ® system.

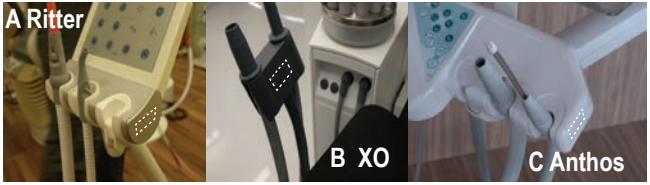
mounting of parking docking

use the universal mounting system
By use of the included universal mounting system the system can be attaced at any place desired. Please take into account in advance the required length of the connection-hose and air-hose. Proceed as follows:

[1] Detemination of Mounting surface

The Yirro-plus® system is preferrably positioned sideways, most right on the assistance unit. (At your mirror hand). If you are left-handed, then choose the opposite side: most left. A surface of 20 x 45 mm wil suffice. Choose a position that minimizes conflicts with the work of your assistant.

Check the available length of the air coupler hose.

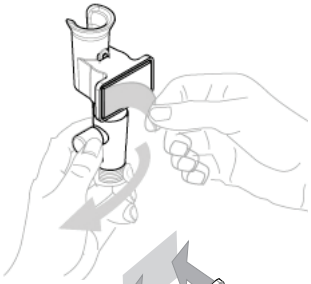


[2] cleaning the mounting-surface

For the purpose of better adhesion the mounting surface needs to be cleaned with alcohol.

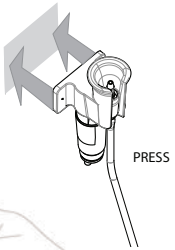
[3] remove adhesive / mount

Remove the adhesive strip and attach the universal suspension.
Press firmly for 20 seconds.



[4] place air-coupler

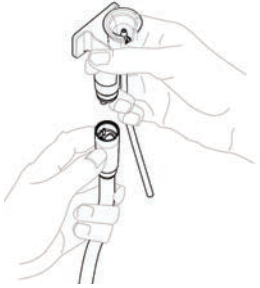
Carefully read the warning text before removing the label of the air-coupler.
Place the air-coupler in the docking.



[5] mounting the connection-hose

Screw the connection-hose to the air regulator.

After cleaning your system is ready for use.

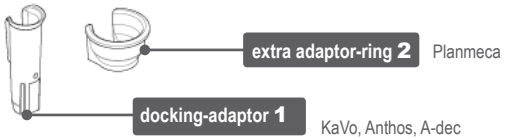


mounting with adaptor docking - ALTERNATIVE

adaptor-docking and adaptor-ring
Sometimes it is possible to place the Yirro-plus® system into a free slot of your assistance-unit (KaVo, Planmeca, Anthos, A-dec). For this purpose in the basic set a adaptor-docking and an adaptation ring are included. (Note: This mounting option is not covered by our CE marking and might possibly conflict to the CE marking of your dental unit.) For dental units of the type KaVo, A-dec and Anthos the docking-adapter 1 can be used. At the Planmeca units, the additional adapter ring nr. 2 is required. Proceed as follows:

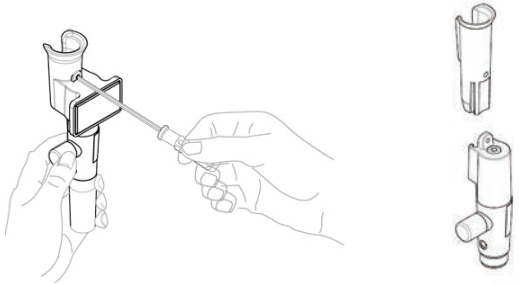
[1] checking the docking-adaptor and adaptor-ring

Planmeca mounting: first mount the extra adaptor-ring [2] into the slot, and afterwards click the docking-adapter [1] into it.)



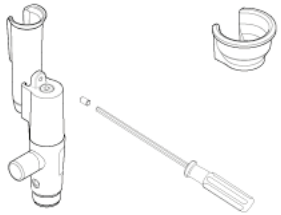
2] r emove universal docking

Loosen the screw and remove the universal docking of the control unit.
Place the universal docking aside and keep the screw at hand.



[3] mounting on air-regulator with screws

Place adaptor-docking (with or without the extra adaptator ring) in the free slot with its opening to the front. Slide the air-regulator into the slots of the adaptor-docking. Screw both parts together by means of the detached [1] screw.

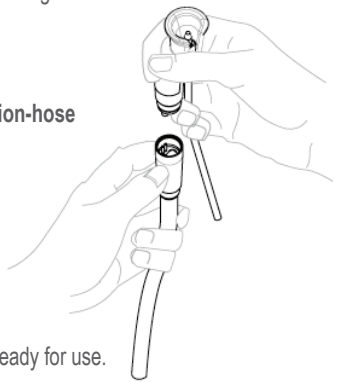


[4] place the air-coupler

Carefully read the text before removing the label information of the air-coupling. Place the air-coupler in the docking.

[5] mounting the connection-hose

Mount the connection-hose to the air-regulator

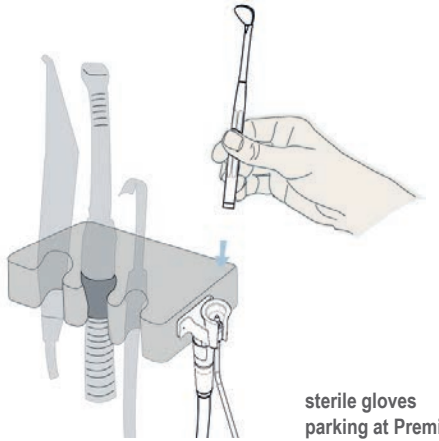


After cleaning the system is ready for use.

parking and switching

Clean handle and mirror head according to standard procedures.

parking (WITHOUT sleeve)
Put on your sterile gloves and take a clean dental mirror. Park it in the parking docking with its head upright. The magnetic air-coupler will snap perfectly into the rear end of the handle.

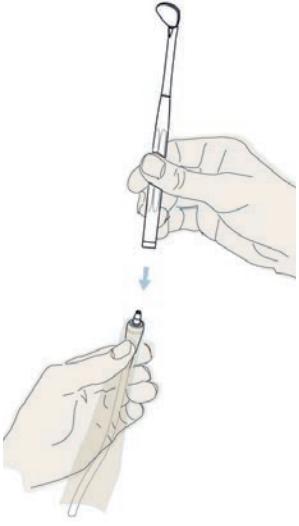


sterile gloves
parking at Premium docking

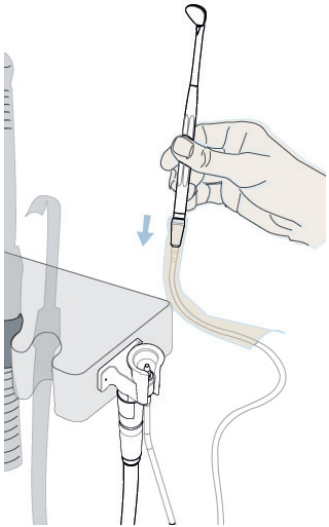
parking - (WITH sleeve)

Clean parking docking and air coupling according to standard procedures. (Alcohol / disinfectant)

parking dental mirrors (WITH sleeve)
Put on your sterile gloves and take the clean magnetic air-coupler from the parking docking. Prick the air-coupler into a sleeve and then click the magnetic coupler on the rear-end of the handle. Place it back in the docking station.



sterile gloves
mounting the sleeve
click coupler at rear-end of handle



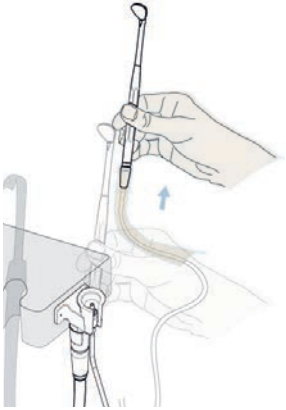
parking the sleeved mouth mirror to docking station

‘on’ and ‘off’ switching through parking

parking and lifting
Through the ‘parking’ and ‘lifting’ of your Yirro-plus ® handle into and from the parking docking you are able to switch ‘on’ or ‘off’ the air flow. It requires a swift movement, that needs a little practice, but without any further extra attention. The system responds to the presence of the magnetic coupler. Replacing the magnet-coupler without the handle will also switch-off the air flow.

lifting: air flow ‘ON’

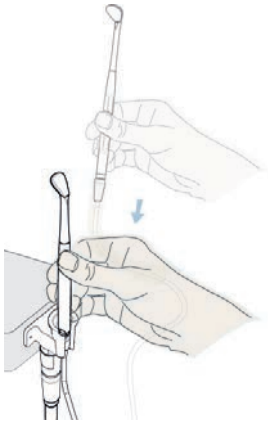
lifting handle: ‘ON’
Remove/lift the parked handle vertically from the docking. The air flow shall start immediately.



lifting; air flow immediately starts working

parking: air flow ‘OFF’

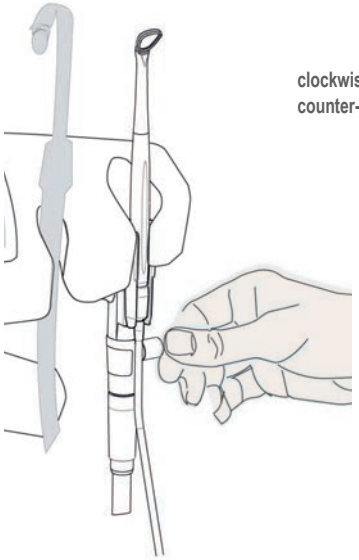
parking: ‘OFF’
Park the mouth mirror back into the docking. The system detects the magnet and the airflow will automatically be switched-OFF.



parking; air flow immediately stops

air regulation - Premium

Set the air strength as desired, by turning the rule knob.
This setting can always be changed, even during treatment.



clockwise: air flow blows softer
counter-clockwise: air flow blows harder

The Premium system is now ready for use.
Clean the parking docking and the magnetic air-coupler carefully with alcohol or disinfectant before each treatment and bsure to always use cleaned handles and mirror heads.

start using the Premium version

start using the Premium version
At every treatment you (or your assistent) follow the hygiene routine:

1 clean in advance the handles and mirror heads through regular methods (thermo-disinfector and / or autoclave)
2 clean the parking docking and the magnetic coupling with alcohol, place the coupling back in the docking
3 if you prefer you can use a sleeve
4 attach the cleaned dental mirror to the magnet coupling and place it back into the docking (=switched OFF)
5 start with the treatment - use the dental mirror any moment you like
6 after every treatment you park the dental mirror into the docking station.
7 repeat steps 1 upto 6

repeated use of clean handles and mirror heads
The Yirro-plus® system is developed for repeated use of cleaned instruments according to hygienic rules. The start set provides you with sufficient handles and mirror heads to work for several hours (4). You should instruct your assistant in advance about the use of the system.

Extra handles and mirror heads are seperately available; also a cleaning box for safely cleaning of 6 mirror heads in a thermodisinfector or autoclave.

cleaning

cleaning instructions
Cleaning handles is possible according to the hygiene directive for cleaning of hollow instruments. The rear-end of the handle fits to the ø4 mm pins and silicone instrument holders of your (Miele) thermodisinfector.

cleaning box
A significant amount of regular damage of instruments is caused by the cleaning process. The special Yirro-plus® cleaning box is a protection box to safely clean 6 mirror heads. This will extend the life of the mirror heads significantly.

malfunction

malfunctions
There is interference in the system in the following situations:

1 air flow does not function
2 parking Yirro-plus® does not switch-off air flow
3 the air regulation does not function
4 the coupler does not click into the handle
5 the mirror head can not be mounted into the handle
6 silicone air-hose is broken or punctured
7 the connection-hose is broken or punctured

Fault 1 airflow does not function
Action: Make sure your air pressure is functioning. If the connection hose is blocked for air, the Yirro-plus® system is not functioning.There may be a problem with the power supply. Both of these aspects are beyond the scope of this manual. If the pressed air system is functioning and if there is no malfunctioning of the electricity, the air hose might be blocked. Contact your service technician.

Fault 2 parking Yirro-plus® does not switch-OFF air flow
Premium: You may not place the the handles far enough into the parking docking, in which case the switch sensor does not detect the magnet. Action: push the handle a little further into the parking docking. If this does not help, check the magnetism of the magnet. See also at nr. 4.

Fault 3 air regulation does not function
Premium: The air flow is controlled by the rotary knob on the air regulator. If turning the knob does not change the flow from hard into soft or vice versa then the regulation system is malfunctioning**.** Action: Make sure that the control knob can be turned. If so, and still no change of air flow occurs, than contact your service technician.

If this is not the case, then the control knob is defect. If you can turn the knob but there is no effect in air force, than the air regulator is defect inside. In both situations you need to contact your service technician.

Fault 4 coupler does not click onto the handle
The magnetic force of your magnet-coupler might have gone lost.
Action: Make sure the magnet in the coupler is functioning by holding it near to a metal object. If the magnet is defect, you can order a new coupler or you can contact your service technician.

Fault 5 the mirror head can not be mounted into the handle
Action: Check the end of the handle. Is this bent, then the handle cannot be used anymore. Use a replacement handle or order a set of new ones. Check if the mirror head clickers are defect. If this is the case, use a replacement mirror head or order a set of new ones.

Fault 6 silicone air-hose is broken or leaks
Action: Pull off the air-hose and order a new air-coupler with hose. You can also contact your service technician.

Fault 7 the connection-hose is broken or punctured
Action: Contact your service technician for a repair.

maintainance

maintainance free
Besides the regular cleaning, your Yirro-plus® system does not require any maintainence. Please clean mirror heads and handles after every treatment by using the regular cleaning procedures. (Thermodesinfector or autoclave). Clean your Premium docking and the air coupling of the Basic coupling after every treatment with alcohol.

REMARK 1: The parking docking contains a sensor and it should NOT be cleaned in the autoclave or thermodesinfector for this reason. Clean your docking with alcohol or other desinfection.

REMARK 2: The air coupler includes a magnet, and the magnetic force might vanish when used in the autoclave. Therefore, DO NOT clean the air coupler in the autoclave or thermodesinfector, but clean it by wiping off with alcohol or other disinfectants.

stop using

stop using
For de-activating of the system, close the air flow through the control knob by turning it OFF. You can ask your service technician to disconnected the system. You can also deconnect the connection-hose.

dismantling and waste

dismantling and waste
The Yirro-plus® system can be dismantled into separate components for separate collection.

environmental aspects

environmental aspects

The raw materials, production and transport processes required for production of the Yirro-plus® system, inevitably pollute the environment. By choosing sustainable materials with a long life and low energy production the environmental load at Yirro-plus ® is minimized. The energy required for the supply of compressed air and for cleaning of the system, are factors that are important for the environment. By using alternative energy sources such as wind or solar power, you help minimizing the environmental aspects when using this system.

vigilance

vigilance

DHM-dental bv is convinced to have done everything possible to this safely and reliably to market this product. To this end, we have followed all the guidelines, discussed with experts and have implemented a quality management system. If you still believe that this product does not meet the qualities and standards that are reasonable to expect, you can report this to the appropriate authorities.

product information

product information

In all packageing and disclaimers of the Yirro-plus ® system you will find the relevant product information and instruction labels / safety ratings according to EN 980:2008. We use the following labels:

Consult instructions for use
The synonym for 'consult instructions for use' is 'consult operating instructions'
This symbol corresponds to the one in ISO 7000-1641 and symbol 5.3 in ISO 15223-1:2007

Symbol for **CE Mark**. This symbol certifies that this product has met European Union consumer safety, health or environmental requirements.

Symbol for **caution**. This safety symbol is used at Yirro-plus® within the context: "attention, see Instructions for Use."

Symbol for **temperature limitation**/temperature range. Both upper and lower limits are indicated adjacent to horizontal lines.

Symbol for **nonsterile**. This symbol should be used only to distinguish between identical or similar devices sold in both sterile and nonsterile conditions.

Symbol for Surgical steel

Symbol forTitanium

Autoclavable at temperature indicated

Symbol for professional use only

Keep magnet coupler away from people with pacemakers or motorised insulin pumps.

Symbol for **serial number.** The manufacturer's serial number is found after or below

Symbol for **batch code/lot number**.
The symbol is accompanied by the manufacturer's batch code.

Symbol for **authorized representative** in the European Community. This symbol is accompanied by the name and address of the authorized representative in the European Community.

Symbol for **manufacturer**. This symbol is accompanied by address and name of manufacturer.

Symbol for **quantity per box**. Any number can be represented in the box.

Symbol for **angle of view of mirrors**. The number indicates the angle in degrees.

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